REMARKS

Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

Rejection of the Claims under 35 U.S.C §112 is not proper

The Examiner has rejected Claims 1-25 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner has asserted that previously amended Claim 1 contains a new negative limitation that cannot be supported in the specification, namely the exclusion of 'chromium yeast' from the chromium-containing compounds envisioned for use in the method of Claim 1. The Examiner has declared that the new limitation is new matter as support for this limitation cannot be found in the Instant Specification. Applicants respectfully disagree.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. M.P.E.P. 2163. Applicants are not permitted to add information that goes beyond the subject matter originally filed when adding or amending the claims of an application.

The Instant Specification provides sufficient disclosure to support the exclusion of chromium yeasts from the possible chromium-containing compounds for use in Claim 1. In order for the exclusionary clause that was added to independent Claims 1 and 16 to have support in the specification, 'chromium yeasts' as a particular chromium-containing compound must be described, as well as the idea of excluding a chromium-containing compound from the group that can be used with the methods of the invention. The specification describes a variety of chromium-containing compounds, without limitation, that can be used with the methods of the invention, including chromium yeasts. The specification does not state that any one particular chromium-containing compound or any particular combination of the chromium-containing compounds described therein must be used in the methods of the invention. One with skill in the art would readily understand that the methods of the invention can be practiced with an individual chromium-containing compound that is described in the specification. Thus, the exclusion of other chromium-containing compounds that are not selected is inherently implied. The specification also describes a preferred embodiment in which the methods of the invention

are practiced with *synthetic* chromium-containing compounds, a subset of the chromium-containing compounds described in the specification. In this preferred embodiment of the invention, non-synthetic chromium-containing compounds such as chromium yeasts would be explicitly excluded.

The amended claims are in full compliance with 35 U.S.C. §112, first paragraph, because all of the elements of the amended claims are supported by the specification. Chromium yeast as a member of the category of chromium-containing compounds is described. The possibility of selecting one chromium-containing compound, to the exclusion of others, in the practice of the methods of the invention would be readily apparent to those with skill in the art. The explicit exclusion of a group of chromium compounds, non-synthetic chromium-containing compounds, of which chromium yeast is a member, is a preferred embodiment of the invention. Thus, all elements of the previously added negative limitation are described. Applicants respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph.

Claims 1-25 are not obvious under 35 U.S.C. §103 in light of de la Harpe and Ostlund

The Examiner had previously rejected the claims as unpatentable under 35 U.S.C. §103 over de la Harpe et al. (US 5,980,905) and Ostlund et al. (US 5,550,166). De la Harpe ('905) describes methods for treating elevated blood glucose and lipid levels with chromium formulations. Ostlund ('166) discloses the use of a carbohydrate compound, pinitol, for the treatment of insulin resistance (IR). The Examiner has alleged that '905 discloses the utility of chromium for the treatment of IR and that '166 discloses the treatment of polycystic ovary syndrome (PCOS) via the treatment of IR. The Examiner has asserted that the claimed methods for the treatment of PCOS with chromium-containing compounds would have been obvious in light of the prior art. Applicants respectfully disagree.

To articulate a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some motivation or suggestion in the prior art to modify the reference. Second, there must be a reasonable expectation of success. Third, the reference must teach all of the limitations of the claims.

The Examiner has maintained the rejection of the claims based on the '905 and '166 patents. However, the rejection of the claims is based on an overly broad interpretation of the prior art. In '905, the effects of chromium depletion in laboratory rats is described to

demonstrate the requirement of adequate dietary chromium in the function of insulin. The Examiner insists that this disclosure would lead one with skill in the art to conclude that, in humans with normal diets who are experiencing insulin resistance, the addition of supranutritional amounts of chromium would be an effective treatment for IR. As '905 does not discuss IR, its causes, or data from animals with normal dietary chromium intake, the Examiner's conclusion is not supported by the '905 disclosure.

The '166 reference describes the use of a carbohydrate compound, pinitol, for the treatment of IR and lists a number of conditions and syndromes in which IR may be present. '166 suggests that pinitol may be useful for the treatment of IR, a condition that may be present in patients diagnosed with PCOS. The Examiner stated in the latest Office Action that the administration of an agent which was known to alleviate insulin resistance "would have treated insulin resistance and thereby offered some beneficial treatment for PCOS or *any disease whereby a symptom of the disease was insulin resistance*" (Page 4, emphasis added). It appears that the Examiner considers IR to be an invariant symptom of PCOS and that by treating IR, other syndromes associated with PCOS would necessarily be treated. Disclosure in the present specification undermines both of these ideas.

Paragraph [0009] of the instant specification describes a study wherein the symptoms of women of three different ethnicities who were diagnosed with PCOS were compared. The study found that women in each group had elevated luteinizing hormone (LH) and testosterone levels, but one-fifth of the women demonstrated no insulin resistance. In another study, detailed in paragraph [0010], only 70% of the women diagnosed with PCOS based on hyperandrogenism and chronic anovulation had elevated levels of LH, demonstrating the variability of the disorders falling under the PCOS definition. Furthermore, the specification states in paragraph [0018] that despite some evidence of an interrelationship between hyperandrogenism and insulin resistance, "this does not completely explain the association between insulin resistance and PCOS", thus other factors are involved. It is clear from the specification that PCOS is a disorder whose indications are numerous, whose definition is being updated using the results of ongoing studies and that there is not a cause-and-effect relationship between PCOS and IR. It is also clear that women can be diagnosed with full-blown PCOS without displaying signs of insulin resistance and that it is erroneous to equate a diagnosis of PCOS with one of IR.

There is no motivation in the combined disclosures to use an agent for the treatment of IR in PCOS patients who do not have a diagnosis of or display symptoms of IR. Contrary to the position of the Examiner, IR and PCOS are not equivalent disorders. Moreover, there is no evidence in the '905 patent that chromium has any utility for treatment of IR, let alone PCOS. The combined disclosure of the prior art does not suggest the administration of chromium for the treatment of IR and does not suggest utility for the treatment of general PCOS with an IR treatment agent without the simultaneous diagnosis of IR. Thus, the prior art fails to teach any of the limitations of the claims. While the disclosure of the'905 reference may provide a reasonable expectation of successfully treating chromium deficiency and associated problems by administering supplementary chromium, without evidence of the utility of chromium in the treatment of IR, one with skill in the art would not have a reasonable expectation of success in treating either IR or PCOS in individuals by administering supplemental chromium based upon the teachings of the prior art references.

The combined disclosure of the prior art would not render the pending claims obvious, due to the lack of motivation to combine the reference teachings, the lack of expectation of success in achieving the claimed invention, and the absence of teachings of the claim limitations. Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. §103.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Final Office Action. Accordingly, the arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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